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K033528

corgenix

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS
MESACUP-2 Test Jo-1
December 2, 2003

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The MESACUP-2 Test Jo-1 is compared to a legally marketed predicate device and a substantial equivalence claim made. The predicate device is Quanta Lite Jo-1 ELISA (K926562) currently manufactured and marketed by Inova Diagnostics, Inc., San Diego, CA.

The MESACUP-2 Test Jo-1 is an enzyme-linked immunosorbent assay (ELISA), utilizing the 96-microwell plate format, similar to the predicate device. Diluted serum samples, calibrator sera, and controls are incubated in microwells coated with Jo-1 (histidyl-tRNA synthetase) antigen. Incubation allows the anti-Jo-1 antibodies present in the samples to react with the immobilized antigen. After the removal of unbound serum proteins by washing, antibodies specific for human immunoglobulins (IgG, IgM and IgA), labeled with horseradish peroxidase (HRP), are added forming complexes with the Jo-1 bound antibodies. Following another washing step, the bound enzyme-antibody conjugate is assayed by the addition of a single solution containing tetramethlybenzidine (TMB) and hydrogen peroxide (H_2O_2) as the chromogenic substrate. The intensity of the color generated is proportional to the serum concentration of anti-Jo-1 antibodies. Optical density is read spectrophotometrically at 450nm. The total incubation time (at room temperature) of the assay is 150 minutes. The assay makes use of two calibrators to measure the amount of anti-Jo-1 antibodies in patient samples.

The intended use of the device is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of anti-Jo-1 antibodies in human serum. as an aid in the diagnosis of polymyositis and/or dermatomyositis, or other related connective tissue diseases.

Performance indicates that MESACUP-2 Test Jo-1 and the Quanta Lite Jo-1 ELISA are equivalent. In-house studies indicate a clinical specificity of 98% and 100% for anti-Jo-1 antibodies in a healthy donor serum population respectively. Additional studies resulted a sensitivity of 100% and 85% with a polymyositis/dermatomyositis population on both assay respectively for anti-Jo-1 antibodies previously also found positive by double immunodiffusion (DID). In general, the performance characteristics are comparable between the two methods. These results are also in compliance with those in published literature for anti-Jo-1 detection.

Nanci Dexter

2003-12-02

Nanci Dexter
Director, Quality Assurance and Regulatory Affairs

Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 2 2003

Rhigene, Inc.
c/o Ms. Nanci Dexter
Director of Quality and Regulatory Affairs
Corgenix Inc.
12061 Tejon Street
Westminster, CO 80234

Re: k033528
Trade/Device Name: MESACUP – 2 TEST Jo-1
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: LLL
Dated: December 2, 2003
Received: December 3, 2003

Dear Ms. Dexter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K033528

Device Name: MESACUP-2 TEST Jo-1

Indications for Use:

The MESACUP-2 TEST Jo-1 is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of anti-Jo-1 antibodies in human serum as an aid in the diagnosis of polymyositis and/or dermatomyositis, or other related connective tissue diseases.

The MESACUP-2 TEST Jo-1 is intended to be used by clinical (hospital and reference) laboratories.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033528